

REMARKS

Claim 2 was cancelled. The right to re-introduce the subject of claims 1-3 and 9-12 in the captioned application or in an application claiming the benefit of priority to the captioned application is expressly reserved.

Claim 5 was amended to specifically recite the subject matter of claim 2, i.e., that the composition is admixed in a comestible. Such amendment was made in view of the disclosure of Sorkin (US Pat. No. 5,952,393). Support for the amendment can be found throughout the specification at, for example, original claim 2.

It is submitted that no new matter has been added by the above amendments.

Indefiniteness Rejection

Claim 13 was rejected under 35 USC §112, second paragraph. (Paper No. 9 at 2.) In making the rejection, the Examiner asserted that "Claim 13 recites a limitation "a method for reducing cholesterol ... administering ... composition of claim 5." (*Id.* at 2.) The Examiner stated that the "preamble of the composition of claim 5 does not include a cholesterol reducing agent." The Examiner suggested "to amend the claim to place it in proper dependent form."

For the reasons set forth below, the rejection is traversed.

The Examiner is asked to review MPEP §2173.05(e). The following is stated in that section:

"A CLAIM IS NOT *PER SE* INDEFINITE IF THE BODY OF THE CLAIM RECITES ADDITIONAL ELEMENTS THAT DO NOT APPEAR IN THE PREAMBLE."

The Examiner has stated no other basis for the rejection. Therefore, the rejection is improper and should be withdrawn.

Anticipation Rejection

The Examiner set forth the introductory paragraphs for a rejection based on 35 USC § 102 (a). (Paper No. 9 at 3.) However, it is not seen where any particular claims were rejected. The Examiner is asked to clarify this ground of rejection in the next paper issued in the captioned application.

Obviousness Rejections

Claims 5-8 and 13 were rejected under 35 USC §103(a) as being unpatentable over Sorkin, US Patent No. 5,952,393 ("Sorkin"). (Paper No. 9 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Sorkin discloses

The present invention provides a composition for reducing serum cholesterol levels in humans and animals. The composition comprises from about 5% to about 75% by weight of phytosterol, and from about 1% to about 60% by weight of policosanol. The composition further comprises from 0% to about 65% by weight of pharmaceutically acceptable formulation aids, such as diluents, stabilizers, binders, buffers, lubricants, coating agents, preservatives, emulsifiers and suspension agents.

In a preferred embodiment, the composition comprises from about 10% to about 60% by weight of phytosterol, and from about 3% to about 46% by weight of policosanol. In the most preferred embodiment of the invention, the composition comprises about 3.2:1 parts by weight of phytosterol and policosanol.

(col. 2, lns. 7-21);

As noted previously, policosanol is a mixture of high-molecular weight aliphatic alcohols. These alcohols occur naturally in wax form and are characterized by fatty alcohol chains ranging from 20 to 39 carbon atoms in length. The major component of policosanol are the aliphatic alcohols octacosanol and triacontanol. Policosanol is isolated from a number of different plant sources, including sugar cane wax and rice bran wax. The policosanol used in the preferred

(col. 2, lns. 26-33);

Phytosterols are also mixtures of long-chained aliphatic alcohols in a wax form. They are naturally occurring in many common vegetable food products. The particular phytosterol used in the preferred embodiment of the invention is derived from vegetable oil and has the formulation set forth in Table 2. This material is sold under the trademark "CHOLESTATIN" and is available from Traco Labs, Inc. Again, however, it should be understood that the invention is not limited to this particular phytosterol product, and that any number of other commonly available phytosterols can be used.

(col. 2, lns. 57-67); and

EXAMPLE 1

Tablet Formula:

ingredient	amount	function
"CHOLESTATIN" (Min. 88% phytosterol)	250 mg.	active
"Rice Bran Wax" (23-33% policosanols)	250 mg.	active
Calcium phosphate	260.7 mg.	base
Cellulose	49.4 mg.	tablet coating
Stearic acid	23.8 mg.	agent
Magnesium stearate	6.8 mg.	lubricant
Silicon dioxide	9.4 mg.	agent

(col. 3, lns. 29-41).

Example 2 was entitled Soft Gelatin Capsule Formulation. (Col. 3, ln. 44).

In making the rejection, the Examiner asserted that "Sorkin teaches a composition for reducing serum cholesterol comprising a mixture of long chain aliphatic alcohols, e.g., policosanol and phytosterol; and binders, coating agents, diluents emulsifiers, suspension agents, or stabilizers." (Paper No. 9 at 3.) The Examiner further asserted that "[t]he mixture of policosanol and phytosterol can be incorporated into a soft gelatin capsule or coated with a tablet coating agent, including cellulose." (*Id.* at 4.) The Examiner contended that "Example 1 also discloses the weight ratio of the long chain aliphatic alcohol to excipients." (*Id.* at 3-4.)

The Examiner acknowledged, however, that Sorkin differs from the presently claimed invention in that "Sorkin does not teach the size of the gelatin capsule being less than about 200 μ m." (Paper No. 9 at 4).

To fill the acknowledged gap, the Examiner merely stated that "no criticality is seen in the particular size." (*Id.* at 4).

The Examiner never concluded, however, that the claimed invention would have been obvious to anyone, much less to one having ordinary skill in the art. The Examiner merely asserted that the burden shifted to the applicant. (*Id.*)

At the outset, the Examiner never made a conclusion that claims 5-8 and 13 were obvious. For this reason, the rejection is improper and should be withdrawn.

Nonetheless, in order to move prosecution of the captioned application forward, the following comments are being provided as if the Examiner had satisfied the requirement for making an obviousness rejection.

Obviousness, however, cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, "cold hard facts."

Initially, it is noted that claim 5 now contains a requirement that the composition be admixed in a comestible. The rejection fails to identify where in Sorkin such a limitation can be found or suggested. Nor is it seen where Sorkin makes such a disclosure. Particularly in view of the disclosure of a tablet and a capsule, where it appears that Sorkin was concerned with oral dosage forms, not with comestibles. For this reason, the rejection cannot stand and should be withdrawn.

In addition, it is noted that claim 2 was not rejected in this particular rejection. The subject matter of claim 2 was incorporated into claim 5 by the above amendments. Therefore, the instant rejection should not apply to amended claim 5.

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The Examiner's assertion that "Example 1 also discloses the weight ratio of the long chain aliphatic alcohol to the excipients" appears not to support the instant rejection. It is submitted that the claimed invention does not require weight ratio of the long chain aliphatic alcohol to the excipients. In fact the claims clearly require, among other things, that the food grade acceptable material be selected from the group consisting of coating polymers, waxes and polymers. Merely asserting "excipients" does not provide any motivation or suggestion to use the specific food grade acceptable material of the claims.

Further, the Examiner asserted that "[c]ontrary to applicant's argument, the excipients taught by Sorkin includes coating agents, which is a generic term, and therefore, permits the present of the claimed food grade acceptable materials, e.g., cellulose polymers and waxes." (Paper No. 9 at 6.) The Examiner's position does not appear to be supported by Sorkin. First, it is not seen where Sorkin discloses "cellulose polymers." Sorkin discloses "cellulose" per se at col. 3. In. 37. It is not seen where a disclosure of "cellulose" per se is a disclosure of "cellulose polymers." Second, the claimed food grade acceptable material is used to encapsulate the alcohol in the claimed invention. It appears that Sorkin discloses wax as an active, i.e., not an excipient. (See col. 2, Ins. 57-58 and col. 3, Ins. 36 and 49.) Finally, for purposes of the claim, the food grade acceptable material is selected from the group consisting of coating polymers, waxes and polymers and it is these materials, not all excipients, that are used to calculate the ratio in the claims. It is not seen where the ratio of alcohol to the food grade acceptable material of the claims is disclosed or suggested by Sorkin. For this reason, the rejection is improper and should be withdrawn.

Claims 5-8 and 13 were rejected under 35 USC § 103(a) as being unpatentable over Sorkin in view of Redding, US Pat. No. 5,271,881 ("Redding"). (Paper No. 9 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.

Sorkin's disclosure set forth above it incorporated herein by reference.

Redding discloses:

SUMMARY OF THE INVENTION

Applicant has discovered an entirely new method
50 and apparatus for producing capsules which does not
limit the range of core and shell materials which may be
used in the encapsulation process and allows the use in
an encapsulation process of core materials and shell
materials not usable with prior art processes. In addition,
the time of encapsulation is reduced. (Col. 4, Ins. 49-54)

TABLE 3		
SOME MICROENCAPSULATION MATRIX AND WALL CHEMICALS		15
<u>Natural Polymers</u>		
Carboxymethylcellulose	Zein	
Cellulose acetate phthalate	Nitrocellulose	
Ethylcellulose	Propylhydroxycellulose	20
Gelatin	Shellac	
Gum arabic	Succinylated gelatin	
Starch	Waxes, paraffin	
Bark	Proteins	1
Methylcellulose	Kraft lignin	1
Arabinogalactan	Natural rubber	1
<u>Synthetic Polymers</u>		25
Polyvinyl alcohol	Polyvinylidene chloride	
Polyethylene	Polyvinyl chloride	1
Polypropylene	Polysiloxane	1
Polystyrene	Polysulfonamide	1
Polysulfonamide	Chlorinated polyethylene	
Polyether	Acetal copolymer	30
Polyester	Polyurethane	
Polyamide	Polyvinylpyrrolidone	
Polyurea	Poly(p-xylene)	1
Epoxy	Poly(methyl methacrylate)	1
Ethylene-vinyl acetate copolymer	Poly(hydroxyethyl methacrylate)	35
Polyvinyl acetate		1
<u>Synthetic Elastomers</u>		
Polybutadiene	Acrylonitrile	
Polyisoprene	Nitrile	
Neoprene	Butyl rubber	1
Chloroprene	Polyisobutylene	40
Styrene-butadiene rubber	Hydri rubber	
Silicone rubber	Ethylene-propylene-diene terpolymer	1

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(Col. 7, lns. 14-44.)

Examples of some liquids which can be used as the liquid medium/solvent are water, hexane, toluene, cyclohexane, and alcohols. Water is often used for colloid materials.

(Col. 22, lns. 65-68.)

In making the rejection, the Examiner asserted that "Sorkin is relied upon for the reason stated above." (Paper No. 9 at 4.)

The Examiner acknowledged, however, that Sorkin differs from the presently claimed invention in that "Sorkin does not teach the size of the encapsulated long chain alcohol." (*Id.* at 4.)

To fill the acknowledged gap, the Examiner relied on Redding for "teach[ing] liquid [sic] core encapsulated by a capsule shell that comprises materials disclosed [sic] in table 3." (*Id.*) The Examiner also pointed out that alcohol can be used in the core and that the capsule has a size range of 5-15 μm . The Examiner then concluded that "it would have been obvious for one of ordinary skill in the art to modify Sorkin's cholesterol lowering composition using the capsule having a size range in view of the teaching of Redding to obtain the claimed invention, because the references teach the desire [sic] for coating alcohol in a capsule shell."

Initially, it is noted that claim 5 now contains a requirement that the composition be admixed in a comestible. The rejection fails to identify where in Sorkin or Redding such a limitation can be found or suggested. Nor is it seen where Sorkin or Redding makes such a disclosure. For this reason, the rejection cannot stand and should be withdrawn.

In addition, it is noted that claim 2 was not rejected in this particular rejection. The subject matter of claim 2 was incorporated into claim 5 by the above amendments. Therefore, the instant rejection should not apply to amended claim 5.

The Examiner's assertion that "Example 1 also discloses the weight ratio of the long chain aliphatic alcohol to the excipients" appears not to support the instant rejection. It is submitted that the claimed invention does not require weight ratio of the long chain aliphatic alcohol to the excipients. In fact the claims clearly require, among other things, that the food grade acceptable material be selected from the group consisting of coating polymers, waxes and polymers. Merely asserting "excipients" does not provide any motivation or suggestion to use the specific food grade acceptable material of the claims.

Further, the Examiner asserted that "[c]ontrary to applicant's argument, the excipients taught by Sorkin includes coating agents, which is a generic term, and therefore, permits the present of the claimed food grade acceptable materials, e.g., cellulose polymers and waxes." (Paper No. 9 at 6.) The Examiner's position does not appear to be supported by Sorkin. First, it is not seen where Sorkin discloses "cellulose polymers." Sorkin discloses "cellulose" per se at col. 3, ln. 37. It is not seen where a disclosure of "cellulose" per se is a disclosure of "cellulose polymers." Second, the claimed food grade acceptable material is used to encapsulate the alcohol in the claimed invention. It appears that Sorkin discloses wax as an active, i.e., not an excipient. (See col. 2, lns. 57-58 and col. 3, lns. 36 and 49.) Finally, for purposes of the claim, the food grade acceptable material is selected from the group consisting of coating polymers, waxes and polymers and it is these materials, not all excipients, that are used to calculate the ratio in the claims. It is not seen where the ratio of alcohol to the food grade acceptable material of the claims is disclosed or suggested by Sorkin. In addition, Redding does not appear to close this gap. For this reason, the rejection is improper and should be withdrawn.

Claims 2-8 and 13 were rejected under 35 USC §103(a) as being unpatentable over Mothes in view of Cain, WO 98/47385 ("Cain"). (Paper No. 5 at 3.)

For the reasons set forth below, the rejection respectfully is traversed.

At the outset, it is not clear which reference the Examiner refers to as Mothes. There are at least six U.S. Patents that list "Mothes" as an inventor. Because the Examiner has not clearly indicated which "Mothes" document the Examiner relied on to make the rejection, the rejection is improper and should be withdrawn.

Solely to expedite prosecution on the merits, it is presumed that the Examiner relied on US Pat. No. 5,961,707 as "Mothes." The Examiner is asked to confirm this presumption in the next paper issued in the captioned application. The following is presented based on this presumption.

Mothes discloses "granules having a relatively high content of ethanol (below 'alcohol') and a process for the preparation of alcohol containing granules by fluidized-bed spray granulation." (Col. 1, Ins. 6-9.) The granules were disclosed as having particle diameters of 0.1 to 2 mm. (Col. 3, Ins. 34-36.) Coating materials for the granules were disclosed as being simple and modified starches, gelatin, cellulose, and cellulose derivatives, lactose, fats, waxes and the like. (Col. 3, Ins. 45-49.) In addition, Mothes discloses that the alcohol-containing granules can serve as additive for a multiplicity of pulverulent foods (for example dry soups, sauces, desserts, beverages etc.). (Col. 3, Ins. 57-60.)

Cain discloses fat-continuous emulsions of fat and water having a fat and an emulsifier system. (p. 2, Ins. 26-29.) The emulsifier system was disclosed as being a blend of components, with emulsifying properties, having components (A), (B), and (C). (p. 2, Ins. 29-32.) A was disclosed as being a partial glyceride, containing at least one fatty acid residue with at least 2 carbon atoms. B was disclosed as being a phospholipid. (p. 3, In. 1.) C was disclosed as being a long chain alcohol having at least 20 carbon atoms in the carbon chain. (p. 3, Ins. 2-3.) Cain disclosed that component (C) is present in a number of natural products such as wheatgerm-wax, carnauba-wax, rice bran wax and sugar cane wax. (p. 3, Ins. 8-10.)

For the reasons set forth below, the rejection respectfully is traversed.

In making the rejection, the Examiner contended that Mothes "teaches alcohol-containing granules coated with waxes, cellulose, gelatin, lactose, or starches. (Paper No. 9 at 5.) The Examiner also asserted that "[t]he alcohol-containing granules can be incorporated into dry soups, sauces, desserts, and beverages." The Examiner then contended that "[a]lthough Mothes is silent as to the teaching of the intended use being claimed... the intended use is inherent since Mothes obtains the same result from the use of encapsulated alcohol as additives useful in dry soups, sauces,

desserts, and beverages.” The Examiner admitted that “Mothes is silent as to the teaching of long-chain alcohol.” (*Id.*)

To fill the acknowledged gap, the Examiner relied on Cain as “teach[ing] long-chain alcohol incorporated in food products, which can be used to provide simultaneously cholesterol-lowering properties.” (Paper No. 9 at 5.) The Examiner then concluded “it would have been obvious for one of ordinary skill in the art to modify Mothes’ alcohol-encapsulated granules using the long chain alcohol in view of the teaching of Cain.” The Examiner reasoned that this is because the “references teach the desires for coating alcohol useful for food products”, which would result in a healthier food product containing encapsulated long-chain alcohol useful to lower cholesterol.

The Examiner also set forth a second conclusion that “it would have been obvious for one of skill in the art to, by routine experimentation modify [sic] the alcohol-containing particle in the beverages taught by Mothes using the long chain alcohol in beverages in view of Cain to obtain the claimed invention.” (Paper No. 9 at 7.) However, this second conclusion is does not rely on the “ordinary skill in the art” standard that is required to make a proper rejection under 35 USC § 103(a). Therefore, to the extent the rejection is based upon this standard, it is improper and should be withdrawn.

In Paper No. 5, at 4, the Examiner set forth a similar rejection. However, in the rejection the Examiner stated “it would have been prima facie obvious.” In the Instant rejection, the Examiner stated “it would have been obvious.” It is respectfully submitted that by removing the term “prima facie” in the instant rejection. The Examiner has admitted that the instant rejection is not a prima facie case of obviousness. Because the Examiner has not made a prima facie case of obviousness, the rejection is improper and should be withdrawn.

Nonetheless, solely to expedite prosecution on the merits, the following is presented:

Obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, “cold hard facts.” When a conclusion of obviousness is not based upon facts, it cannot stand.

The Examiner asserted that “the subject matter [sic] disclosed in the reference” is the reason for combining the references. The Examiner then contended that the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

However, the Examiner's contention ignores binding precedent concerning the mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness. See *In re Fritch*, 23 USPQ 1780, 1783 (Fed. Cir. 1992).

Mothes defined ethanol as being the alcohol that was the subject of the document. (Col. 1, Ins. 6-9.) As admitted by the Examiner, Mothes does not disclose the claimed long chain alcohol. **The record contains no evidence of the equivalence between ethanol and the long chain alcohol, which are affirmatively required in the claims of the captioned application.** It is not seen where all alcohols have the same properties as the carbon chain increases in size. Absent such evidence the record is devoid of any reason as to why one of ordinary skill in the art would look to an encapsulated ethanol when trying to encapsulate long chain alcohols of the present invention.

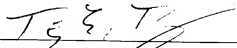
The Examiner is asked to provide evidence pursuant to MPEP § 2144.03 and 37 CFR 1.104(d)(2) as to the interchangeability of ethanol with the long chain alcohols of the present invention. Without such proof, it is submitted that the Examiner is merely undertaking impermissible hindsight reconstruction of the present invention. "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. Because the rejection fails to satisfy the burden placed on the Examiner, the rejection is improper and should be removed.

Because the rejection **again** fails to satisfy the burden placed on the Examiner, the rejection is improper and should be withdrawn.

Serial No. 10/023,177

Accordingly, entry of the amendments and allowance of the claims is respectfully requested.
If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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Dated: June 6, 2003